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Section 6 – Traditional 510(k) Notification: -Summary

This Traditional 510(k) notification is to provide substantial equivalence for Advanced Medical Solutions Limited's Silver Alginate IV Antimicrobial Wound Dressing, which is substantially equivalent to currently marketed devices intended for wound care.

Submitted by:-

Advanced Medical Solutions Limited
Road Three
Winsford Industrial Estate
Winsford, Cheshire
CW7 3PD
United Kingdom

Contact:-

Mrs Claire Ryan
Regulatory Affairs Manager
Telephone: + 44(0)1606 545569
Fax:- + 44(0)1606 863600
Email: claire.ryan@admedsol.com

Date prepared:- 14th February 2008

Common Name:- Silver Alginate IV Antimicrobial Wound Dressing

Trade Names:- Not yet defined

Classification Name:- Dressing, Wound, Drug

Classification:- Unclassified

Product Code:- FRO

Legally marketed device(s) for substantial equivalence comparison:-
Silver Alginate II Dressing, 510(k) # K041316/K063173/K070581, manufactured by Advanced Medical Solutions.
Aquacel Ag with hydrofibre (Absorbent Antimicrobial Wound Dressing), 510(k) # K013814, manufactured by ConvaTec, A division of E.R Squibb and Sons LLC.

Device Description:-
Silver Alginate IV Antimicrobial Wound Dressing is a sterile, non woven pad or rope/ribbon/filler composed of a high M (mannuronic acid) calcium alginate, carboxymethylcellulose (CMC) and ionic silver complex (silver carbonate), which releases silver ions in the presence of wound fluid. As wound fluid is absorbed the dressing forms a gel, which aids autolytic debridement, whilst maintaining a moist environment for optimal wound healing and allows intact removal.

The silver ions protect the dressing from a broad spectrum of microorganisms, such as *Staphylococcus aureus,* including MRSA, *Staphylococcus epidermidis,* including MRSE, *Streptococcus pyogenes, Enterococcus faecalis (VRE), Pseudomonas aeruginosa, Escherichia coli,* and fungi such as *Candida albicans* , over a period of up to twenty-one (21) days, based on in-vitro testing, and may reduce odour caused by micro-organisms in the wound. Odour reduction results from the antibacterial effect in the dressing.

Silver Alginate IV Antimicrobial Wound Dressing is an effective barrier to bacterial penetration.

The dressing has pale golden appearance and is available in various sizes (5cm x 5cm, 10cm x 10cm, 10cm x 12cm, 15cm x 15cm, 10cm x 20cm, 20cm x 30cm flat dressings; 2.7cm x 30cm and 3cm x 44cm flat rope dressings; and 30cm x 2g rope dressings). The dressings are packaged in pouches.

Indications for use:
Silver Alginate IV Antimicrobial Wound Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, such as pressures ulcers, diabetic ulcers, leg ulcers, post-operative wounds, trauma wounds (dermal lesions, trauma injuries or incisions), graft and donor sites, post-operative surgical wounds, 1st and 2nd degree burns. Silver Alginate IV Antimicrobial Wound Dressing is indicated for external use only.

Manufacturing:-
Silver Alginate IV Antimicrobial Wound Dressing will be manufactured according to the product specification and under good manufacturing practices (GMP). A risk analysis has been performed to identify possible failure mode during manufacturing. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode.
Advanced Medical Solutions Ltd meets all the established specifications prior to release to ensure the device is safe, effective and correctly labelled for its intended use.

Testing:-
The biocompatibility of Advanced Medical Solutions Limited Silver Alginate IV Antimicrobial Wound Dressing has been demonstrated to be in compliance with the requirements of BS EN ISO 10993-1(Biological Evaluation of Medical Devices). Sterilisation validation has been performed in compliance with harmonised standards.

Statement of Substantial Equivalence:-
The indication for use, performance testing and antimicrobial activity for the Silver Alginate IV Antimicrobial Wound Dressing is substantially equivalent to the predicate devices; Silver Alginate II Dressing, 510(k) # K041316/K063173/K070581, manufactured by Advanced Medical Solutions and Aquacel Ag with hydrofibre (Absorbent Antimicrobial Wound Dressing), 510(k) # K013814, manufactured by ConvaTec, A division of E.R Squibb and Sons LLC. The biocompatibility and performance testing for the Silver Alginate IV Antimicrobial Wound Dressing has demonstrated that the device is safe and effective for the indications of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2008

Advanced Medical Solutions Ltd
% Ms. Claire Ryan
Regulatory Affairs Manager
Road Three, Winsford Industrial Estate
Winsford, Cheshire, CW7 3PD
United Kingdom

Re: K080503
Trade/Device Name: Silver Alginate IV Antimicrobial Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 30, 2008
Received: November 3, 2008

Dear Ms. Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Silver Alginate IV Antimicrobial Wound Dressing**

Indications for Use:

Silver Alginate IV Antimicrobial Wound Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, such as:

- Post-operative wounds
- Trauma wounds (dermal lesions, trauma injuries or incisions)
- Leg Ulcers
- Pressures Ulcers
- Diabetic Ulcers
- Graft and donor sites
- Post-operative surgical wounds
- 1st and 2nd degree burns
- Partial and Full Thickness wounds

Silver Alginate IV Antimicrobial Wound Dressing is indicated for external use only

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Milkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080503